

**REMARKS**

Claims 1 and 11-22 are pending in the application. By this Amendment, claim 1 is amended. No new matter is added by this amendment, and this amendment is supported fully by the specification. It is respectfully submitted that claims 1 and 11-22 are in condition for allowance in view of the amendments and remarks presented herein.

**SUMMARY OF ACTION**

Claims 1 and 11-22 are pending in the above-captioned application. The Office Action rejects claims 1, 12-16, and 20-22 under 35 U.S.C. § 103(a) as being unpatentable over McMullin et al. (EP 0-747-067 A2) in further view of Janzen et al. (U.S. Patent No. 5,523,291). The Office Action objects to claims 11 and 17-19 as being dependent upon a rejected base claim.

**Claim Rejections - 35 U.S.C. § 103(a)**

The Office Action rejects claims 1, 12-16, and 20-22 under 35 U.S.C. § 103(a) as being unpatentable over McMullin et al. (EP 0-747-067 A2) in further view of Janzen et al. (U.S. Patent No. 5,523,291). The rejection is respectfully traversed.

The Office Action asserts that McMullin et al. discloses “a moldable collagen composition used in tissue repair and augmentation which comprises fibrillar collagen and a particulate matter (see Abstract)” and that such collagen material “must be purified (non-cytotoxic) and non-antigenic (see page 3, lines 44-45).” The Office Action further asserts that “[f]ibrillar collagen is the natural state of collagen (original architecture, and is rendered nonfibrillar for the non-particulate portion of the composition) (see page 4, lines 4-9)” and that the particles sizes can range from 100 microns to 1000 microns. The Office Action also states the compositions taught by McMullin et al. “may be injected using glycerol as part of the carrier

(see page 5, line 59, page 6, line 1)” and the final product is moldable and has a doughy texture (paste) (as disclosed at page 5, lines 36-38).”

McMullin et al. discloses a multi-component moldable collagen-containing composition that includes (a) a non-fibrillar collagen material and (b) a particulate material. McMullin et al. utilizes a non-fibrillar collagen that is either non-fibrillar at the outset or is a fibrillar material that is rendered non-fibrillar by the addition of a fiber disassembly agent. *See, e.g.*, page 4, lines 3-9. Thus, the composition of McMullin et al. is solubilized and/or reconstituted and, as a result, the original fiber architecture and molecular ultrastructure is lost. *See, e.g.*, page 3, lines 42-46. In contrast, Applicants’ invention, as recited in claim 1, preserves the original fiber architecture and molecular ultrastructure of the collagen material from which it is derived. Thus, the invention of claim 1 requires the collagen material to retain its original fiber architecture and not be deconstructed into its fibril form as described in McMullin et al.

Additionally, the structure disclosed in McMullin et al. forms an amorphous, virtually structureless mass following injection *in vivo*. In contrast, Applicants’ invention provides a structure resistant to calcification and granulation.

The Office Action further states that McMullin et al. does not disclose the use of elastin, but that Janzen et al. discloses the use of elastin in such collagen-containing compositions. Janzen et al., however, fails to supply the deficiencies of McMullin et al. In particular, Janzen et al. does not disclose using a fibrillar collagen that preserves “the original fiber architecture and molecular ultrastructure of the natural tissue material from which it is derived” as required by independent claim 1. Thus, the combination of McMullin et al. and Janzen et al. fails to provide the invention recited in independent claim 1 and the corresponding dependent claims.

Moreover, McMullin et al. and Janzen et al. do not provide the requisite motivation to combine or modify their teachings to arrive at the invention recited in independent claim 1 or the corresponding dependent claims. Thus, it is respectfully submitted that McMullin et al. and Janzen et al. fail to teach or suggest the invention recited in independent claim 1 or the corresponding dependent claims. Therefore, withdrawal of the rejection of claims 1 and 11-28 under 35 U.S.C. § 103(a) based upon McMullin et al. in view of Janzen et al. is respectfully requested.

### CONCLUSION

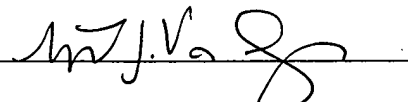
In view of the foregoing, Applicants respectfully request reconsideration and timely allowance of the pending claims. Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact Applicants' undersigned representative to expedite prosecution.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1349. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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